

**510(k) Summary of Safety and Effectiveness**

Triathlon® CS (Condylar Stabilizing) Lipped Insert

JAN 22 2007

Proprietary Name: Triathlon® CS (Condylar Stabilizing) Lipped Insert

Common Name: Modular Tibial Insert

Classification Name/Reference: Knee Joint Patellofemorotibial  
Polymer/Metal/Polymer Semi-Constrained  
Cemented Prosthesis  
21 CFR §888.3560

Knee Joint; Patellofemorotibial; Metal/polymer;  
Porous-coated; Uncemented prosthesis  
21 CFR 888.3565

Device Product Code: 87 JWH  
87 MBH

Proposed Regulatory Class: Class II

For Information contact: Sheryl R. Bagalio, RAC Regulatory Affairs  
Specialist  
Howmedica Osteonics Corp.  
325 Corporate Drive  
Mahwah, NJ 07430  
Phone: (201) 831-5314 Fax: (201) 831-6038

Date Summary Prepared: January 10, 2007

**Description:**

The Triathlon® CS (Condylar Stabilizing) Lipped Insert is compatible with the standard Triathlon® CR (Cruciate Retaining) and Triathlon® PS (Posterior Stabilizing) femoral components as well as the Triathlon® Primary Cemented, Triathlon® Beaded Baseplates, the Triathlon® Universal Baseplate and the Triathlon® Low-Profile Baseplate. The Triathlon® CS Lipped Insert features a similar anterior constraint to the Triathlon® CR insert which allows the surgeon to retain or sacrifice the Posterior Cruciate Ligament (PCL).

**Intended Use:**

The Triathlon® CS (Condylar Stabilizing) Lipped Insert is intended for use in primary and revision total knee arthroplasty to alleviate pain and restore function. The

Triathlon® CS (Condylar Stabilizing) Lipped Inserts will be provided sterile and are for single use only.

#### Indications For Use:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis), or rheumatoid arthritis
- Post-traumatic loss of knee joint configuration and function
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability
- Revision of previous unsuccessful knee replacement or other procedure
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture management techniques

#### Contraindications

- Any active or suspected latent infection in or about the knee joint.
- Distant foci of infection which may cause hematogenous spread to the implant site.
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the prosthesis.
- Skeletal immaturity.
- Severe instability of the knee joint secondary to the absence of collateral ligament integrity and function.
- Obesity. An overweight or obese patient can produce loads on the prosthesis which can lead to failure of the fixation of the device or to failure of the device itself.

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#### Substantial Equivalence:

The Triathlon® CS (Condylar Stabilizing) Lipped Insert is substantially equivalent to other modular tibial inserts regarding intended use, design, materials, and operational principles such as the Duracon® CS Lipped Tibial Insert cleared under K021451, K023724 and K032163, the Triathlon® CR Tibial insert cleared under K040267, K042883 and K051146, and the Triathlon® PS insert cleared under K031729, K050539 and K051146. Range of Constraint and Contact Area/Peak Stress was presented to compare to other tibial inserts on the market. The results demonstrate that the subject components are substantially equivalent to the predicate components.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Howmedica Osteonics Corporation  
% Sheryl R. Bagalio, RAC  
Regulatory Affairs Specialist  
325 Corporate Drive  
Mahwah, New Jersey 07430

JAN 22 2007

Re: K063423  
Trade/Device Name: Triathlon® CS (Condylar Stabilizing) Lipped Insert  
Regulation Number: 21 CFR 888.3560  
Regulation Name: Knee joint patellofemoral tibial polymer/metal/polymer semi-constrained cemented prosthesis.  
Regulatory Class: Class II  
Product Code: JWH, MBH  
Dated: January 10, 2007  
Received: January 12, 2007

Dear Ms. Bagalio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

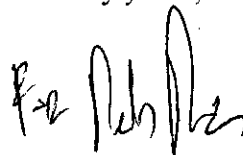
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', written in a cursive style.

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known): K063423

Device Name: Triathlon® CS (Condylar Stabilizing) Lipped Insert

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- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.

- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the prosthesis.
- Skeletal immaturity.
- Severe instability of the knee joint secondary to the absence of collateral ligament integrity and function.
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Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



**(Division Sign-Off)**

**Division of General, Restorative,  
and Neurological Devices**

**510(k) Number**   16063423